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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/976,328	10/12/2001	Bernd Aldefeld	DE 000174	9218

24737 7590 07/23/2003

PHILIPS INTELLECTUAL PROPERTY & STANDARDS
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EXAMINER

SMITH, RUTH S

ART UNIT

PAPER NUMBER

3737

DATE MAILED: 07/23/2003

8

Please find below and/or attached an Office communication concerning this application or proceeding.

NK

Office Action Summary	Application No.	Applicant(s)
	09/976,328	ALDEFELD ET AL.
	Examiner	Art Unit
	Ruth S Smith	3737

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 15 May 2003.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.
- 4) Claim(s) 1-15 is/are pending in the application.
 - 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1-15 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on 15 May 2003 is: a) approved b) disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
 - a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) <input type="checkbox"/> Notice of References Cited (PTO-892)	4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)
3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____	6) <input type="checkbox"/> Other: _____

Drawings

The proposed drawing correction and/or the proposed substitute sheets of drawings, filed on May 15, 2003 have been approved. A proper drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The correction to the drawings will not be held in abeyance.

Claim Objections

Claims 1-9,11-13,15 are objected to because of the following informalities: In claim 1, lines 5-6, "the end zone of the medical instrument" lacks antecedent basis. Claim 11 is incomplete in that it fails to positively set forth any structure of a medical instrument Appropriate correction is required.

Claim Rejections - 35 USC § 112

Claims 13-15 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The specification fails to disclose any computer program with program sections for executing the method as set forth in the claims or for controlling the device as set forth in the claims or the medical instrument .

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of

the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1,2,5,9-11,13-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Manwaring et al. Manwaring et al disclose an apparatus including an endoscope for providing live video images 44, an imaging means for providing and storing survey images 42 and localization means which located the position of the endoscope and superimposes such on the survey image. The localization means uses a magnetic field sensor 30' and an external measuring device 28. The apparatus includes a computer for carrying out the method of using the apparatus as seen in the flow charts provided. With respect to claim 5, the sensing coils are inherently detectable by a magnetic resonance device or an ultrasound device. Manwaring et al disclose placing the sensor 30' on the handle and determining the location of the tip (end zone) using the known fixed relationship between the location of the sensor and the location of the tip relative to the sensor. In the absence of any showing of criticality or unexpected results, placing the sensor 30' at the tip or a fixed distance from the tip would have been a matter of obvious engineering design choice that would not result in any different outcome during the use of the device. Placing the sensor at either the tip or a known fixed distance from the tip would allow a user to easily determine the position of the tip using the position determining means set forth.

Claims 3,12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Manwaring et al as applied to claims 1,11 above, and further in view of Van Vaals et al. Manwaring et al fails to specifically disclose the use of catheter and a microcoil and MRI system used as a localization means. Van Vaals et al disclose an a catheter having localization means including a microcoil used with a magnetic resonance imaging

system to locate the position of the catheter. It would have been obvious to one skilled in the art to have further modified Manwaring et al such that the localization means is as disclosed by Van Vaals. Such a modification merely involves the substitution of one known type of localization means. It should be noted with respect to claim 12, that an endoscope is considered to be a type of catheter.

Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over Manwaring et al as applied to claim 1 above, and further in view of Slettenmark. Manwaring et al fails to specifically disclose the use of an ultrasound localization means. Manwaring et al disclose that instead of a magnetic localization means an acoustic means can be used. Slettenmark is just one example of many which disclose the use of an ultrasound localization means. It would have been obvious to one skilled in the art to have modified Manwaring et al such that the localization means is an ultrasound localization means. Such a modification merely involves the substitution of one known type of localization means for another.

Claims 6,12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Manwaring et al as applied to claims 1,11 above, and further in view of Dickinson et al or Ben-Haim et al. Manwaring et al fails to specifically disclose the use of an intravascular ultrasound device as a means to provide the live video. Ben-Haim et al and Dickinson et al each disclose an intravascular ultrasound catheter which provides images around the tip of the catheter. The catheter further includes means for locating the position of the catheter in the body using a magnetic localization means. It would have been obvious to one skilled in the art to have further modified Manwaring et al such that the endoscope is replaced with an intravascular ultrasound imaging catheter. Such a modification merely involves the substitution of one known type of invasive imaging probe for another.

Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over Manwaring et al as applied to claim 1 above, and further in view of Ozawa et al. Manwaring et al fails to specifically disclose the use of an OCT device as a means to

provide the video images. Ozawa et al disclose an endoscope which includes an OCT device for providing images inside a patient. It would have been obvious to one skilled in the art to have further modified Manwaring et al such that the endoscope used includes an OCT device for providing the live images. Such a modification merely involves the substitution of one known type of invasive imaging probe for another.

Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over Manwaring et al as applied to claim 1 above, and further in view of Wendt et al. Manwaring et al fails to specifically disclose the use of an MR probe as a means to provide the video images. Wendt et al disclose an MR probe that can be placed in the body in combination with means outside the body to provide images. It would have been obvious to one skilled in the art to have further modified Manwaring et al such that the endoscope is replaced with an MR imaging catheter. Such a modification merely involves the substitution of one known type of invasive imaging probe for another. It should be noted that the placement of the probe in any desired position in the patient would have been obvious to one skilled in the art depending upon where the procedure is to be carried out.

Response to Arguments

Applicant's arguments filed May 15, 2003 have been fully considered but they are not persuasive. Manwaring et al disclose placing the sensor 30' on the handle and determining the location of the tip (end zone) using the known fixed relationship between the location of the sensor and the location of the tip relative to the sensor. In the absence of any showing of criticality or unexpected results, placing the sensor 30' at the tip or a fixed distance from the tip would have been a matter of obvious engineering design choice that would not result in any different outcome during the use of the device. Placing the sensor at either the tip or a known fixed distance from the tip would allow a user to easily determine the position of the tip using the position determining means set forth. The specification fails to disclose any example of a computer program

with program sections for executing the method as set forth in the claims or for controlling the device as set forth in the claims or the medical instrument.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ruth S Smith whose telephone number is (703) 308-3063. The examiner can normally be reached on M-F 5:30 AM- 2:00 PM.

The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3590 for regular communications and (703) 308-0758 for After Final communications.



Ruth S Smith
Primary Examiner
Art Unit 3737

RSS
July 19, 2003